DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 3, 2014

Karl Storz Endoscopy-America, Inc.
Winkie Wong
Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, CA 90245-5017

Re: K140964
Trade/Device Name: Calculase II
Regulation Number: 21 CFR§ 878.4810
Regulation Name: Powered Laser Surgical Instrument
Regulatory Class: II
Product Code: GEX
Dated: April 11, 2014
Received: April 17, 2014

Dear Winkie Wong,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140964

Device Name
Calculase II

Indications for Use *(Describe)*
The laser is used to create laser energy for the destruction of calculi and/or for soft tissue treatments such as the cutting of tissue and the opening of stenosis and strictures during endoscopic urological applications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant:	Karl Storz Endoscopy-America, Inc 2151 E. Grand Avenue EI Segundo, CA 90245
Contact:	Winkie Wong Regulatory Affairs Specialist 424-218-8379 424-218-8519
Date of Preparation:	April 11, 2014
Device Identification:	Trade Name: Calculase II Common Name: Powered Laser Surgical Instrument Classification Name: Powered Laser Surgical Instrument
Product Code:	GEX
Regulation:	CFR 878.4810
Predicate Device(s):	AURIGA QI (K121570)
Device Description:	The KARL STORZ Calculase II is a Ho-YAG desktop laser that emits a mid-infrared beam at the wavelength of 2080nm with pulse energy of 500-2000mJ and pulse frequency of 4 – 15Hz. The laser energy is transmitted into the tissue via an optical fiber, with the maximum limit of the laser energy set at 20W. The laser energy generated by Calculase II enables the optimal lithotripsy of all calculus compositions in the human body and soft tissue treatment such as the ablation of strictures and stenosis, for example.

	Calculase II is a desktop unit designed to be mobile so that it can be easily transported and placed on top of a desk or cart and positioned within the treatment room by using special, retractable handles located on the both sides of the desktop units. All controls and displays required for operating the unit (On/off switching key, fiber connection port, power setting.. etc.) are located on the front of the device in a user-friendly control panel and easy-to-read LED displays, which make the unit safe and easy to operate by the users. The 1-pedal footswitch allows the users to release the laser to the intended area during use. The Calculase II Holmium Laser system uses a flexible laser fiber, inserted into an endoscope (flexible, semi-rigid and rigid) through the urethra or percutaneously to fragment and vaporize the calculi stone located in the bladder, urethra, or kidney. With the proper energy level setting, it can also perform soft tissue treatments such as ablation of strictures and stenosis. For lithotripsy, proper energy level should be set depending on the fiber diameter, hardness of stone, and location of the stone. The laser emission is activated by a footswitch pedal, which allows the operator to be "hands-free" for specific target fragmentation. With the fiber placed lightly against the stone or soft tissue in the contact procedure, pulses of energy are used to fragment and vaporize the stone or ablate strictures and stenosis. As the laser beam is concentrated on the target area, the surrounding tissue can relax, cool and dissipate the heat in between the short bursts. This way the target tissue sustains cumulative thermal effect with maximum protection of the surrounding area.
Indications For Use:	The laser is used to create laser energy for the destruction of calculi and/or for soft tissue treatments such as the cutting of tissue and the opening of stenosis and strictures during endoscopic urological applications
Technological Characteristics:	The predicate and subject devices are both Holmium Laser System that emit laser energy at the wavelength of 2080nm. However, due to the limitation of the indications of the subject device compared to the predicate, they have minor differences in the technological characteristics. These differences are: • The subject device has a maximum energy output as

	20W, whereas the predicate has the maximum energy output as 30W; a difference of 10W in maximum energy. • The range for pulse duration for the subject device is 100 – 500 μs, whereas the predicate device's range for pulse duration is 200 – 500 μs; a difference of 100μs in the lower limit for pulse duration. • The ranges for the frequency and pulse energy for the subject device are 4 – 15 Hz and 500 – 2000 mJ, respectively, whereas the predicate device has the ranges for the frequency and pulse energy are 4 – 20 Hz and 200 – 4000 mJ, respectively; a difference of 5 Hz in the upper limit of the frequency range, 300 mJ in the lower limit and 2000 mJ in the upper limit of the pulse energy's range. The bench test data for the Calculase II Holmium Laser System demonstrates that the design characteristics used as the basis for the comparison have been met. The results show that the subject device has met all its specifications. The performance validation test report, System Test Record, is provided in section 021_Performance Testing of this submission. Combining the minor difference in specifications with the limited indication of use in the Calculase II compared to the predicate device, Auriga QI, Calculase II does not raise new issues of safety and effectiveness and the devices are substantially equivalent for urological application.
Non-Clinical Performance Data:	Calculase II is tested according to the following standard: • IEC 60601-1 • IEC 60601-1-2 • IEC 60601-2-22 • IEC 60825-1 Additional bench testing for performance verification and validation purposes: • Max Output • Pulse Duration • Frequency

	• Pulse Energy The bench testing performed verified and validated that the Calculase II has met all its design specification and is substantially equivalent to the predicate device, AURIGA QI, for urological procedures.
Clinical Performance Data:	No clinical information is required for this submission
Conclusion:	The Karl Storz's Calculase II is substantially equivalent to its predicate devices. The non-clinical testing demonstrates that the device is as safe and effective as the legally marketed devices.